UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TEXAS MARSHALL AND LUFKIN DIVISIONS

COOPERVISION, INC.,) Case No. 2:06-CV-149 RHC) Case No. 9:05-CV-260 RHC
Plaintiff,) Case No. 9.03-C v-200 KHC
v) JURY
CIBA VISION CORPORATION,)
Defendant.)
	<i>)</i>

CooperVision Inc.'s Opening Claim Construction Brief

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I. Introduction

Plaintiff CooperVision, Inc. submits this brief in support of its proposed patent claim constructions in the above captioned cases. There are two families of patents in suit: (1) the Edge Design Patents – U.S. Patent Nos. 6,431,706 and 6,923,538; (2) the Toric Patents – U.S. Patent Nos. 6,467,903; 6,857,740; 6,971,746; 7,133,174; 7,134,753. The patents within a family share a common specification. All specification references in the Edge Design Patents and Toric Patents sections of the brief are to the '706 and '903 patents respectively.

The technologies implicated by the Edge Design and Toric Patents are discussed at length in CooperVision's Technology Synopsis. This brief is intended to be read in concert with the Synopsis.

II. Legal Standards for Claim Construction

Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). "The duty of the trial judge is to determine the meaning of the claims at issue, and to instruct the jury accordingly." *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995) (citations omitted).

The starting point for a claim construction is "how a person of ordinary skill in the art understands a claim term." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). "[T]he person of ordinary skill in the art is deemed to read the claim term . . . in the context of the entire patent, including the specification." *Id.* The specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). *See also id.* at 1316 ("The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.") (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir.1998)). Differences among the claims of a patent "can also be a useful guide in understanding the meaning of particular claim terms." *Id.* at 1314.

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"[E]xtrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* at 1318. Expert testimony can provide context for even non-technical claim terms. *See Tap Pharmaceutical Products, Inc. v. Owl Pharmaceuticals, L.L.C.*, 419 F.3d 1346, 1354 (Fed. Cir. 2005) (holding that the non-technical term "containing" "cannot be defined by some ordinary meaning isolated from the proper context, and it was appropriate for the district court not only to consider the intrinsic evidence" but also to consider an expert's interpretation of that evidence "both in context and from the perspective of a person of ordinary skill in the art.").

The Federal Circuit has warned against relying on dictionaries, especially non-technical dictionaries, to define the scope of claim terms. *See Anderson v. Int'l Eng'g & Mfg., Inc.*, 160 F.3d 1345, 1348-49 (Fed.Cir.1998) ("[D]ictionary definitions of ordinary words are rarely dispositive of their meanings in a technological context. A word describing patented technology takes its definition from the context in which it was used by the inventor."); *see also Phillips*, 415 F.3d at 1321 ("The main problem with elevating the dictionary to such prominence [over the specification] is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent. . . . [H]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification.").

Indeed, if a dictionary definition is inconsistent with the specification, the meaning in the specification must prevail. *See In re Johnston*, 435 F.3d 1381, 1384 (2006) ("It is well established that dictionary definitions must give way to the meaning imparted by the specification") (citing *Phillips*).

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In construing claim terms, the Federal Circuit has cautioned that "while we cannot import limitations from the preferred embodiments into the claim, we also should not normally interpret a claim term to exclude a preferred embodiment." *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 848 (Fed. Cir. 2006).

III. Edge Design Patents

There is a common thread running through the parties' proposed claim constructions of the Edge Design Patents. CIBA wants the claims to be limited to a single embodiment: both the back and front peripheral edges of the inventive lens must each consist of a single radius of curvature which combine to create a perfectly circular edge. CIBA's constructions are fundamentally inconsistent with the express language of the specification, which makes clear that: (1) a convexly-curved peripheral surface does not require a single radius of curvature, but rather can include one or more curves and one or more flats; (2) the front face edge of the lens need not have a rounded shape; indeed, a significant utility of the invention is that the front peripheral surface can include a standard edge shape that is not curved.

A. Person of Ordinary Skill in the Art

A person of ordinary skill in the art of the '538 patent would have a degree in engineering, physics, or optometry, three to five years working experience designing contact lenses, and knowledge of contact lens material properties, contact lens manufacturing, and clinical evaluation of contact lens performance. Declaration of Ronald G. Seger, O.D. ("Seger Decl."), ¶ 7.

B. "[B]ack surface tool including . . . a convexly curved second surface portion circumscribing the first surface portion" ('706 patent, claim 1)

"[T]he surface of the tool including . . . a second surface portion defining a convex curved outer peripheral edge surface of the insert" ('706 patent, claim 15)

<u>CooperVision Proposed Construction</u>: "A 'convex[ly] curved surface' is an outward facing curved surface containing a continuous curve, or a series of flats, or a combination of one or more curves and one or more flats." "A 'second surface portion circumscribing the first surface portion' is the outer peripheral edge surface."

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<u>CIBA Proposed Construction</u>: "[A] second surface portion that circumscribes the first surface portion and the entire second surface portion is curved outward like the exterior of a sphere so as to produce a contact lens with a rounded edge."

Claim 1 of the '706 patent describes a method of making a contact lens that involves the use of an uniquely-shaped tool to make the back surface mold of the contact lens. That back surface tool has a "convexly curved second surface portion circumscribing the first surface portion." The claim does not place any explicit limits on the actual shape of the contact lens produced using this method. Nor does it place any limits on the shape of the tool use to make the front surface mold of the contact lens.

Claim 15 describes a surface tool with a convex curved peripheral edge used to make a mold for one face of a contact lens. It does not discuss the shape of the tool used to make the mold for the opposite face of the lens, nor the shape of the lens.

There are two points of dispute between the parties regarding the construction of these elements: (a) what constitutes a "convex[ly] curved" peripheral edge surface of a back surface tool; (b) whether a limitation requiring that the method of claim 1 produce a lens with a "rounded edge" or that the tool of claim 15 produce a "rounded edge" should be read into the claim.

1. A Convexly Curved Surface Can Include Multiple Shapes

CIBA's definition of "convexly curved . . . surface" requires the presence of a single radius of curvature (*i.e.*, a section from a perfect circle) across the entire peripheral edge surface of the back surface tool. CIBA's interpretation is inconsistent with the specification which makes explicit that a "convex[ly] curved . . . surface" is not limited to a single radius of curvature that spans the entire peripheral edge of the back surface. In contrast, CooperVision's construction, which makes clear that a convexly-curved peripheral edge surface can include both curved and flat surfaces, is explicitly supported by the specification:

"[T]he present invention purposefully places at least one convex radius, or curve, at the outer or peripheral edge of a back surface tooling. This convex radius can be generated by a series of flats, for example, very short flats which together closely simulate continuously curved

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convex shaping, **or by a combination of flats and convex curves** on the tooling insert." 6:65-7:4 (emphasis added); *see* 3:40-50 (same).

In addition to explicit examples of the type of shapes that can make up a convexly curved surface, there are also general statements in the specification establishing that the peripheral edge surface can contain more than a single radius of curvature. For example, the specification describes "the present invention" as a back surface tool with "a convex curve" or "at least one convex curve" "along an outer radius." 2:31-36; 6:46-51 (emphasis added). The indefinite article "a" and the term "at least one" make clear that something other than a single radius of curvature can reside on the peripheral edge surface. *See Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.3d 1357, 1370 (Fed. Cir. 2002) ("It is well settled that the term 'a' or 'an' ordinarily means 'one or more.").

The Federal Circuit has held that it is improper to adopt a construction of a term that excludes a preferred embodiment described in the specification. Yet that is exactly what CIBA proposes. All of the above quoted language appears in sections of the specification entitled "Summary of the Invention" and "Description of the Present Invention." 2:23; 4:41 (emphasis added). The language makes clear that an integral part of the invention includes placing shapes on a convexly-curved peripheral edge surface other than a single radius of curvature.

CIBA's proposed construction also renders nonsensical dependent claims in the patent.

Claim 15 of the '706 patent describes a back surface tool with a "convex curved outer peripheral surface." Both parties agree that this language has the same meaning as claim 1's "convexly curved second surface portion." Dependent claim 17 specifies the "convex curved outer peripheral surface" includes a "combination of curves and flats." CIBA's construction of the "convex curved outer peripheral surface" requires the presence of a single radius of curvature, which means that CIBA's interpretation of claim 15 excludes its dependent claim 17. CIBA's construction violates a fundamental principle of claim construction: An independent claim must be construed to cover each of its dependent claims. See Robotic Vision Systems, Inc. v. View Engineering, Inc., 189 F.3d 1370, 1376 (Fed. Cir. 1999) ("View's construction incorrectly

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attributes the requirement of separately fabricated index pads to an independent claim when it is clear that a claim that depends from that independent claim does not incorporate that limitation.").

2. <u>Importing a Rounded Edge Limitation Is Improper</u>

Claim 1 of the '706 patent recites the presence of a back surface tool with a convexly curved second surface portion. The claim makes no reference to the design of the front surface tool, nor does it make any reference to the shape of the contact lens produced as the last element of claim 1. Despite this, CIBA attempts to import its definition of "rounded edge" into two separate limitations in the claim. CIBA's construction of the first element of claim 1 requires that the back surface tool "produce a contact lens with a rounded edge." Likewise, its construction of the fourth element of claim 1 replaces the term "contact lens member" with a "contact lens member with a rounded edge." Joint Claim Construction Statement ("JCS"), Amended Attachment A, at 1, 11. (The original and amended claim charts for the JCS are attached as an appendix to this brief.)

CIBA adopts a very similar strategy with claim 15, which describes a surface tool with a convex curved peripheral edge surface that is used to make a single mold section. Despite the complete absence of any discussion of the shape of the tool used to make the opposite mold section, much less a discussion of the shape of lenses made using the tool, CIBA requires that this tool "be useful in making a lens with a rounded edge." JCS, Amended Attachment A, at 1. It also replaces the preamble's reference to "a contact lens" with "a contact lens with a rounded edge." *Id.*, at 12.

CIBA is advancing a definition of "rounded edge" that requires both the front and back surface of the lens to have a mathematically perfect circular shape: "shaped like a portion of a circle in which every part of the surface or circumference is equidistant from a center point." As discussed in the next section, this is an improper definition of "rounded edge" in the context of the patents. Even if it were a proper definition, however, it has no place in claims 1 and 15, which contain no limitations on the shape of the front surface of the lens.

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Moreover, CIBA's construction makes superfluous dependent claim 2, which has only one limitation: the contact lens member of claim 1 having "a rounded edge." The Federal Circuit instructs that the "presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips*, 415 F.3d at 1314-15. The presumption is "especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim." *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

3. Peripheral Edge Surface and Second Surface

CIBA's proposed construction describes the location of the convex[ly]-curved surface" in claims 1 and 15 as the "second surface portion that circumscribes the first surface portion." This construction does not assist the jury in understanding the meaning of these claims. A second surface portion that circumscribes a first surface portion is an outer peripheral edge surface. This is confirmed by the specification, which uses the phrase "second surface" in only one passage: "[t]o form the rounded edge surface of the final lens product, the surface of the tool includes a first surface portion in the general shape of a lens face, preferably a posterior lens face . . . and a second surface portion defining a convex curved outer peripheral edge surface." 3:40-45. To the extent CIBA seeks to define a second surface portion in any other manner, its construction is improper. This proposed construction was not included by CooperVision in the JCS.

CooperVision believes it is appropriate to construe this term, however, because CIBA's amended claim construction position (filed on May 11) suggests that the parties do not agree on the meaning of second surface as used in claim 1 of the '706 patent.

C. "[C]ontact lens having a rounded edge" ('706 patent, claim 4)

<u>CooperVision Proposed Construction</u>: "A 'contact lens having a rounded edge' is a contact lens having a posterior surface in a general shape of an insert tool that includes a first posterior surface portion and a convexly curved second posterior surface portion that circumscribes the first posterior surface portion."

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<u>CIBA Proposed Construction</u>: "[A]n edge that is shaped like a portion of a circle in which every part of the surface or the circumference is equidistant from a center point."

1. <u>CIBA's Construction of Rounded Edge Ignores the Specification's Description of</u> "The Invention"

The specification is explicit that a contact lens with a rounded edge is a contact lens with a back surface that corresponds to the shape of a back surface tool with a convexly curved peripheral edge surface. No limitations are placed on the shape of the front surface of the lens.

The specification explains that "to form the rounded edge contact lens, the back surface tool having a convex curve along the outer radius thereof" is used to create a back surface mold. 2:55-60. "The second mold section may be made in a conventional manner and preferably generally defines a negative impression of a front, or anterior, surface of the contact lens." 2:61-64. The two mold halves are then assembled and a lens is formed. "Upon demolding . . . a fully molded, contact lens member having a rounded edge form or surface is obtained." 2:67-3:3; *see* 6:46-63 (creating a "contact lens member having a rounded edge form" by assembling mold sections, one of which is formed with "a back surface tool having a surface corresponding to a desired contact lens surface and at least one convex curve along an outer radius thereof ").

What defines whether a contact lens edge is "rounded" is the shape of the back surface tool used to make it, not its front surface. The statement in the specification that the front surface mold can be made in the "conventional manner" establishes that the front surface need not have any rounding. Indeed, the specification depicts the shape of "conventional [front surface and back surface] mold halves" in Figure 1A. Ex. A (annotated version of Figure 1A); 4:58-61; *see also* 5:26-30 (referring to Figure 1B). The front surface mold in Figure 1A, far from having a perfectly circular shape, has a flat taper.

The specification consistently defines a lens with a rounded edge solely with reference to its back surface shape:

• "[T]he present invention comprise[s] providing . . . a back surface tool . . . having a convex curve along an outer or peripheral radius. . . . [T]he convex curve of the tool,

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- when used to form a back surface mold section, provides a contact lens having the desired rounded edge form " 2:31-54.
- "To form the rounded edge surface of the final lens product, the surface of the [back surface] tool includes . . . a second surface portion defining a convex curved outer peripheral edge surface " 3:40-45.

Moreover, as discussed in the previous section, the specification is explicit that the back surface tool with a convexly-curved peripheral edge surface need not consist of a single radius of curvature (i.e., a portion of a perfect circle). It can include a combination of one or more curves and one or more flats. 6:64-7:4.

By inserting a "rounded edge" limitation into every asserted claim in the patent, and by advancing an interpretation of this term that requires both the front and back peripheral surfaces to have a perfectly circular shape, CIBA ignores the express teaching of the patent: (1) there are no limits placed on the shape of the anterior surface insert tool, or the anterior surface of the lens; (2) as discussed in the previous section, a convexly curved peripheral edge surface can include shapes other than a single radius of curvature (*i.e.*, a portion of a perfect circle).

In addition to ignoring the express teaching of the specification, CIBA's definition excludes the edge shape depicted in Figure 8 of the patent. The specification describes Figure 8 as depicting the shape of a mold pair used to form "a rounded edge contact lens in accordance with a method of the present invention." Of course, Figure 8 does not depict a shape in which either the posterior or anterior edges have a perfectly circular shape. To the contrary it depicts, on the posterior peripheral edge, a convexly curved surface that includes at least one flat. Moreover, its front surface mold shape includes a flat taper on its anterior face. Attached as Exhibit B is an annotated version of Figure 8 identifying these features.

The specification contemplates that lenses covered by the invention can have different levels of peripheral edge roundness. For example, the specification teaches that increasing the size of the angle at which the front and back surface molds meet ("angle of interface") can increase the roundness of a lens edge. 7:34-47. Thus, an angle of interface between the posterior

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and anterior molds of 140 degrees can lead to the "much more rounded" lens edge in Figure 3 after the molded lens material is hydrated." *Id.* Figure 3, however, represents only one embodiment of the invention. It is for this reason that the '706 patent contains <u>dependent</u> claims that require angles of interface between posterior and anterior molds of greater than 100 degrees (which encompasses the mold used to make the lens of Figure 3). *See* '706 patent, claims 5-6, 10-11.

2. <u>CIBA's Construction Robs the Edge Design Patents of a Critical Disclosed</u> Utility.

Part of the utility of the invention is that it allows a lens designer to create a rounded edge lens while still using a front surface mold shape "made in a conventional manner," such as those depicted in Figures 1A and 1B. 2:65-3:1. Placing a convexly curved peripheral edge surface on the back of the inventive lenses shifts whatever sharp edge may exist on the edge of the lens away from the surface of the eye, regardless of the shape on the front surface of the lens. Seger Decl., ¶¶8-9. It is for this reason that the specification places no limits on the edge shape of the front face of the contact lens.

The ability to use a conventional front surface mold shape has a practical utility, because a lens designer seeking to create the inventive lens need not necessarily adjust pre-existing front surface edge designs. Seger Decl., ¶9. It also has a clinical value. A number of considerations go into the design of the edge shape for the front face of a lens. For example, if a lens is too thick at its edge, it will be uncomfortable. Because the front face need not be rounded at its edge, the invention gives a lens designer more flexibility to take into account other considerations when designing the front face. *Id*.

D. "A lens body . . . having an anterior face, a posterior face having a rounded outer peripheral edge" and related limitations ('538 patent, claims 1 and 7; '706 patent, claim 13)

Claims 1 and 7 of the '538 patent and 13 of the '706 patent contain limitations that use the phrase "rounded outer peripheral edge." JSC, Amended Attachment B, at 8. For example, claims 1 and 7 of the '538 patent recite "a lens body . . . having an anterior face, a posterior face having a rounded outer peripheral edge surface extending from the anterior face to the posterior

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face. . . . " In the last element of each of these claims, the shape is referred to as simply a "rounded" "outer peripheral edge surface."

<u>CooperVision Proposed Construction</u>: "A contact lens with an anterior face, and a posterior face having a surface in a general shape of an insert tool that includes a first surface portion and a convexly curved peripheral edge surface."

CIBA Proposed Construction: CIBA does not want the Court to construe the entire phrase quoted in the heading of this section. It only wants the Court to construe the limitation "a rounded outer peripheral edge surface extending from the anterior face to the posterior face."

JCS, Attachment A, at 10. According to CIBA, this requires "[a]n edge that is shaped like a portion of a circle in which every part of the surface or the circumference is equidistant from a center point."

CIBA's reason for ignoring part of the limitation is clear. It proposes a definition that requires that both posterior and anterior face of the lens have a perfectly circular shape. This definition, however, is inconsistent with the plain language of claims 1 and 7, which requires that the "posterior face hav[e] a rounded outer peripheral surface extending from the anterior face to the posterior face." The claims say not a word about the shape of the anterior face.

The definitions proposed by the parties for claim elements that include the phrase "rounded peripheral edge" reproduce the dispute regarding the meaning of "rounded edge" in claim 4 of the '706 patent. CIBA requires that both the front and back peripheral surface of the lens have a perfectly circular shape. And CooperVision believes that this interpretation is fundamentally inconsistent with the specification, which makes clear that only the back surface need have a convexly-curved peripheral edge surface.

There are two features of note regarding the asserted claims that contain the "rounded peripheral edge" limitation.

1. '706 Patent, Claim 13

Claim 13 of the '706 patent contains different language from claims 1 and 7 of the '538 patent. It describes a lens with an "anterior face, a posterior face, and a rounded peripheral edge

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surface " Claims 1 and 7 of the 538 patent recite a "<u>posterior face having</u> a rounded outer peripheral edge." Thus, whereas it is absolutely explicit in claims 1 and 7 that the "rounded peripheral edge surface" is describing a shape on the posterior of the lens, an interpretation of claim 13 requires that the claim be read in light of the specification.

Claim 13 requires that the back surface mold used to make the inventive lens contains "a concave outer peripheral edge surface." But it places no limitation on the edge shape of the mold for the front face of the lens. This is consistent with the express teaching in the specification, which not only fails to place any limits on the edge shape of the front face tool, mold or lens, but affirmatively instructs the reader that the mold shape can be made in a "conventional manner," such as those depicted in Figures 1A and 1B. 2:61-64; 4:15-16. Just as in the case of claims 1 and 7 of the '538 patent, a "rounded peripheral edge surface" describes the shape of the back surface of the lens: a back surface formed by a back surface tool with a convexly-curved peripheral edge surface.

CIBA also appears to concede that the difference in language between claim 13 and claims 1 and 7 does not alter the scope of the claim. Thus, it proposes that all of these claims require a perfectly circular front and back surface edge.

2. "Extending from the anterior face to the posterior face"

Claims 1 and 7 of the '538 patent recite "a posterior face with a rounded peripheral edge extending from the anterior face to the posterior face." *See also* 706 patent, claim 13 ("a rounded peripheral edge extending from the anterior face to the posterior face.") The plain language of claims 1 and 7 make clear that the language "extending from . . ." simply describes the rounded shape on the peripheral edge of the back surface of the lens. This is consistent with the specification, which places no limits on the shape of the front face of the inventive lens, but instead instructs that it can be made in a mold formed in "a conventional manner." 2:61-64.

CIBA also appears to concede that the "extending from . . ." language does not add any additional limitations to the claims in which it appears, because regardless of whether a claim has this additional language, CIBA advances the identical definition of "rounded . . . edge." For

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example, CIBA interprets claim 4 of the '706 patent, which recites the presence of a "rounded edge," but does not contain the "extending from the anterior face to the posterior face" language, as requiring a perfectly circular shape on the edges of both the anterior and posterior faces. This is the same definition CIBA applies to "a rounded peripheral edge" in '706 patent claims 1 and 7, and '706 patent claim 13. The logical conclusion of CIBA's position is that the language "extending from the anterior face to the posterior face" does not add any additional meaning to the "rounded peripheral edge" limitation.

E. "[T]he lens body formed by a process including cast molding using a first polymeric mold section having a surface in a general shape of a negative of the posterior face and a concave outer peripheral surface" ('538 patent, claims 1 and 7; '706 patent, claim 13)

'538 patent claims 1 and 7 and '706 patent claim 13 recite a lens that has a "rounded peripheral edge" formed by a back surface mold with a "concave outer peripheral surface." The specification defines a mold with a "concave outer peripheral surface" in terms of the tool that makes the mold. For example, it states that "[t]he portion of the back surface tool that forms the lens periphery is convex in form Correspondingly, the first mold section formed by the tooling insert has a concave outer edge surface." 3:16-20. Indeed, the specification consistently describes the shape of the back surface mold used to create an inventive lens as a "negative" of the back surface tool with a convexly-curved peripheral surface that created the mold. 2:40-52; 6:48-57. CooperVision's proposed definition remains true to the specification by defining a mold with a "concave outer peripheral surface" as the negative of a tool with a "convexly-curved peripheral edge surface."

F. "[E]nhanced lens wearer comfort [scleral safety] relative to an identical contact lens without the rounded outer peripheral edge ('538 patent, claims 1, 2, 7)

<u>CooperVision Proposed Construction</u>: "The rounded outer peripheral edge surface of the lens provides a clinically relevant increase in user comfort [or scleral safety]."

<u>CIBA Proposed Construction</u>: Although CIBA now contends that this element needs no construction, in both the original and revised P.R. 4-3 submissions to the Court, it acknowledges that the evidence of enhanced lens wearer comfort and scleral safety required by claims of the

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'538 patent must be "objective:" "Objectively improved lens wearer comfort [or scleral safety] relative to an identical contact lens that does not have a rounded outer peripheral edge." JCS, Attachment A, at 15-18; Amended Attachment A, at 9.

Both parties appear to agree that the limitations require an improvement in scleral safety and lens wearer comfort that is not anecdotal. They just cannot agree on whether "objective" or "clinically relevant" is the most appropriate term to describe this concept.

CooperVision is uncomfortable with the term "objective" because it does not accurately describe how data is collected on clinical performance of lenses. For example, standardized guidelines for the contact lens industry make clear that user comfort can be measured by surveying the subjective responses of users using a numerical psychometric scale. Seger Decl., ¶10. When the data is aggregated, it becomes "clinically relevant."

IV. Toric Patents

The Federal Circuit's decision in *Phillips* makes clear that the single most important tool for construing the claims of a patent is the specification. "Usually, it is dispositive." 415 F.3d at 1313. CIBA's claim construction positions for the Toric Patents not only fail to find support in the specification, they are inconsistent with what the specification describes as the preferred embodiments of the invention.

A. Person of Ordinary Skill in the Art

A person of ordinary skill in the art of the Toric Patents will have a degree in optometry, physics or engineering, coupled with 3-5 years of experience designing contact lenses, including lenses with rotational stabilization structures. Seger Decl., ¶11.

B. Annotated Figures

The Toric Patents use a number of terms to describe regions of a contact lens that practices inventions disclosed in the patents. Attached as Exhibits C, D, and E are annotated versions of Figures 1, 3, and 4A in the specification which correlate locations on inventive lenses with the terminology used in the Toric Patents. The annotations are based on the descriptions of the figures given in the specification. 5:50-6:43; 7:9-21; 7:31-65; 8:40-9:10.

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C. Transition Areas

CooperVision introduces the concept of Transition Areas in its proposed construction for claim limitations containing the term "inner zone." JCS, Amended Exhibit B, at 10. CIBA introduces the concept of Transition Areas (which it calls "boundar[ies]") in its proposed construction for claim limitations containing the term "peripheral zone." *Id.*, at 9. The parties agree that there can be transition areas between different zones of a lens. The parties disagree on how to describe the transition areas.

<u>CooperVision Proposed Construction</u>: "a rounded or curved transition or a discrete boundary, discontinuity, or corner (a 'Transition Area')" between zones on the lens.

<u>CIBA Proposed Construction</u>: "a curved or rounded transition (*i.e.*, an area of the lens that creates a smooth junction between adjacent curvatures) or . . . a discrete boundary, discontinuity or corner (collectively, 'boundary')."

The only point of dispute between the parties is that CIBA describes a transition as "an area of the lens that creates a smooth junction between adjacent curvatures." This additional language finds no support in the specification. The specification describes a transition as a means of connecting two surfaces on a lens. For example, the specification notes that "the exemplary lens of the present invention possesses gradually curved transitions between the zones." 5:65-6:3. If any additional gloss is put on the term "transition," it should be language consistent with the specification: a transition is an area of the lens that connects separate portions or surfaces on a lens.

D. "[P]eripheral zone . . . adjacent the peripheral edge" of the lens ('903 patent, claims 29, 34, 38; '740 patent, claim 1; '746 patent, claim 1)

<u>CooperVision Proposed Construction</u>: "A portion of the lens with a decreasing thickness to provide a ramp from a ballast periphery to the lens edge, to create a comfort zone around the edge of the lens."

<u>CIBA Proposed Construction</u>: "A zone or region on the anterior face of the lens that is tapered thinner toward the peripheral edge of the lens, is located adjacent to the peripheral edge of the lens, and that circumscribes and is separated from the inner zone by [a boundary]. The

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boundary separating the zones is the only such identifiable boundary between the peripheral edge and the boundary of the optic zone."

1. The Inner Zone Ends At the Ballast Periphery

The specification defines the peripheral zone as that area of the lens that begins at the ballast periphery and decreases in thickness to the lens edge. Fig. 1; 6:4-13; 6:21-32; 7:37-50; 9:49-52; 10:13-21. For example, the specification defines the inner zone as region 26 in Figure 1 and the peripheral zone as region 24. 5:50-61; Ex. C (annotated version of Figure 1). The dividing line between these two points is labeled 34. The specification explains that "the peripheral zone 24 desirably exhibits taper so as to be thinner at the lens edge than at the circular ballast periphery 34." 6:5-7 (emphasis added); 6:21-32 (defining 34, the dividing line between the inner and peripheral zone, as "the circular ballast periphery."); 10:16-22 ("the transition between the peripheral zone and the inner zone" is at the "circular ballast periphery 34."). Thus, the dividing line between the inner zone and the peripheral zone is expressly defined by the specification as the ballast periphery.

The specification also describes the peripheral zone as creating a comfort zone around the edge of the lens. 9:5-10; 10:7-13. Because of the ramped comfort zone, "movement across the contact lens is facilitated, and there is less irritation." 9:6-7.

2. CIBA's Construction Places Arbitrary Limits on Lens Design

CIBA agrees that the peripheral zone is an area of decreasing thickness toward the edge of the lens: "a zone or region . . . that is tapered thinner toward the peripheral edge of the lens. . . ." CIBA, however, places an arbitrary limitation on the beginning of the peripheral zone, noting that "[t]he boundary separating the [inner and peripheral] zones is the only such identifiable boundary between the peripheral edge and the boundary of the optic zone." According to CIBA, every inventive lens will have one and only one transition area between the optic zone and the peripheral edge of the lens. This limitation is inconsistent with both the specification and with how lenses are designed.

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The specification does not place any limits on the number of transitions or discontinuities between the optic zone and the peripheral zone. Moreover, the preferred embodiment actually contemplates the presence of multiple Transition Areas within the inner and peripheral zones. Figure 4a is a map of the anterior face of a preferred embodiment lens showing the thickness of the lens at different points. 4:54-56. The data make clear that there are changes in the rate of increase or decrease in thickness within the inner zone and within the peripheral zone. A standard method of altering the rate of increase or decrease in thickness is to place separate surfaces on the lens, the surfaces producing different thickness, which are then connected by Transition Areas. Seger Decl., ¶12.

Figure 4a identifies the inner zone as region 26 and the peripheral zone as region 24. 8:40-57. Attached as Exhibit E is an annotated version of the figure highlighting the thickness profile along the vertical meridian below the optic zone (identified as position A on the figure). The thickness profile of the lens along the vertical meridian beginning in the inferior portion is as follows: 240-250-260-270-280. This represents a constant rate of increasing thickness. After 280, however, there is a decrease in thickness to 240. This decrease in thickness occurs before the beginning of the peripheral zone (represented by the dotted line).

Referring to position B on Figure 4a, there are at least two additional differences in the rate of thickness decrease in the peripheral zone: between 240 and 210 (a change of negative 30) and between 210 and 140 (a change of negative 70). Thus, along the vertical meridian from the beginning of the inner zone to the peripheral edge, the rate of thickness increase or decrease changes three times: 270-280-240 (positive 10 to negative 40), 280-240-210 (negative 40 to negative 30), 240-210-140 (negative 30 to negative 70). Each of these points of change represents a potential Transition Area.

In other locations on the lens, there are changes in the rate of decrease in thickness (and thus potential Transition Areas) within the optic zone: At position B there is a change in the rate of thickness increase from positive 5 (95-100) to positive 20 (100-120). This point of change represents a potential Transition Area.

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Every claim in the '903, '740 and '746 patents expressly recites the presence of a peripheral zone. CIBA's proposed construction means that there is not a single claim in the Toric Patents that covers the standard method of implementing a preferred embodiment lens of Figure 4a.

E. Inner [Second] Zone ('903 patent, claims 29, 34, 38; '746 patent, claim 1; '740 patent, claim 1; '753 patent, claim 15; '174 patent, claim 16)

The asserted independent claims all have very similar phrases which introduce the concept of an inner or second zone. For example, Claim 1 of the '746 patent describes "an inner zone of the anterior face circumscribed by the peripheral zone and surrounding the optic zone." The parties agree that all of these elements should receive the identical interpretation. JCS, Amended Exhibit B, at 10-11. But the parties disagree on the proper interpretation.

<u>CooperVision Proposed Construction</u>: "A portion¹ of the lens circumscribed by the peripheral zone and that surrounds the optic zone. The lens may include [a Transition Area] between the inner zone and the optic zone and [a Transition Area] between the inner zone and the peripheral zone."

CIBA Proposed Construction: "A zone or region on the anterior face of the lens that is circumscribed by the peripheral zone and surrounds the optic zone (or has a portion that surrounds the remainder of the inner zone that makes up the optic zone). The inner or second zone is separated from the optic zone (or the portion of the inner zone that makes up the optic zone) by a boundary. The outer edge of the inner or second zone (where the inner or second zone meets the peripheral zone) is also separated from the peripheral zone by a boundary, which is the only identifiable boundary between the peripheral edge of the lens and the boundary of the optic zone."

CIBA appears to agree that the inner zone is between the optic zone and the peripheral zone. CIBA, however, once again insists that there is only a single Transition Area on the lens outside of the optic zone. As discussed above, this serves to exclude a preferred embodiment of

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¹ In the JCS, CooperVision's proposed construction for this term inadvertently used the phrase "zone or region" instead of "portion."

the patent, in which Transition Areas can exist within the inner and peripheral zones. It also is unsupported by the specification, which places no limits on the number of Transition Areas within a zone.

CIBA's construction, although difficult to parse, also appears to maintain that the only region separating the optic zone from the inner zone is what it describes as a "boundary" (*i.e.*, a Transition Area). Any construction that precludes the presence of additional zones or regions on the lens other than the optic, inner, and peripheral zones is inconsistent with the plain language of the asserted claims, which allow for the possibility of additional zones.

The asserted independent claims describe lenses "comprising," "including," or having a "plurality of zones . . . including" certain specific zones. The Federal Circuit has repeatedly held that the transition phrase "including" and "comprising" allow for the presence of unrecited structures or features. *See SanDisk Corp. v. Memorex Products, Inc.*, 415 F.3d 1278, 1284 (Fed. Cir. 2005) ("As a patent law term of art, 'includes' means 'comprising.' Neither includes, nor comprising, forecloses additional elements that need not satisfy the stated claim limitations. Nor does the choice of articles . . . "a plurality ") (citations omitted). Moreover, CIBA agrees that "plurality" means "two or more." *See* JCS, Amended Attachment B, definition of "a plurality of isothickness bands," at 6. It is therefore improper to interpret these claims as limited to only the recited zones:

- '903 patent, claims 29, 34, and 38: the claimed contact lens "comprising . . ."

 "wherein the anterior face defines a plurality of zones thereon, including an inner zone . . . the peripheral zone . . . and an optic zone." (emphasis added)
- '746 patent, claim 1: the claimed contact lens "comprising" an "anterior face including an inner zone . . . the peripheral zone, and an optic zone." (emphasis added)
- '740 patent, claim 1(part of asserted claims 8 and 11): the claimed contact lens
 "comprising . . . " an optic zone, inner zone, and peripheral zone (emphasis added)

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• '174 patent, claim 16 (part of asserted claim 25) and '753 patent, claim 15: the claimed contact lens "comprising an optic(al) zone; and a second zone"

(emphasis added)

Moreover, the specification makes clear that inventive lenses can have more than three zones. For example, the Summary of the Invention states that "[t]he anterior face defines a plurality of zones thereon, including an inner zone circumscribed by the peripheral zone, and an optic zone defined generally in the middle of the inner zone." 3:24-27 (emphasis added); 4:5-8 ("a plurality of zones thereon, including"). This makes clear that the specification does not intend to limit the zones that can be present on a lens.

F. "[T]he thickness is substantially equal on the left side region of the second zone and the right side region of the second zone" ('753 patent, claim 15)

<u>CooperVision Proposed Construction</u>: "The second zone includes a series of cross-sections that each has a substantially uniform thickness not varying by more than about 30 μm or 20% of the minimum thickness within the cross-section. The area of the second zone to the left of the vertical meridian has a thickness topography that is symmetric with a thickness topography of the area of the second zone to the right of the vertical meridian."

<u>CIBA Proposed Construction</u>: "At any given horizontal cross-section, the thickness is approximately the same across the entire horizontal cross-section on the left side region of the second zone and the right side region of the second zone."

Claim 15 of the '753 patent requires that each cross section in the second zone (*i.e.*, the inner zone, exclusive of the optic zone and the peripheral zone) has substantially uniform thickness. CooperVision's proposed definition reflects this concept.

CIBA agrees that the relevant area of analysis is the entire second zone. CIBA also appears to accept, based on its proposed definition of second zone, that the relevant area of analysis excludes the optic zone and peripheral zone. *See* JCS, Amended Attachment B, "a second zone circumscribing . . .", at 10-11. Finally, CIBA agrees that there must be some type of uniformity in thickness within any given cross section in the second zone. The dispute appears to be about what this means.

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CIBA describes the uniformity in thickness in each cross section with the phrase "the thickness is approximately the same " CIBA has replaced the claim language "substantially equal" with the phrase "approximately the same." CIBA's construction does nothing to assist a jury in understanding the claim. The claim language must be interpreted in light of the specification. The specification makes clear that any variance in thickness within a cross section that is no "more than about 30 μ m or 20%" is acceptable. 7:22-30; 6:55-58. Indeed, it is for this reason that both parties agree that when terms use the phrase "substantially uniform thickness" without any numerical limitation, it means a thickness "that does not vary by more than 30 μ m or 20% of the minimum thickness with the cross-section." JCS, Amended Attachment B, at 5. It is appropriate, therefore, to interpret a claim limitation requiring that a give cross-section have "substantially equal" thickness in a manner consistent with the purposes of the inventions as disclosed in the specification, which is to limit variance in thickness in a cross section to a specific critical range – less than 30 μ m or 20%.

Finally, CIBA's requirement that the cross-sections analyzed are "horizontal" imports an additional limitation not present in the claim. The limitation that the cross-sections analyzed are horizontal is present in dependent claims 16 and 17. It is not proper to read this limitation into the independent claim 15: the "presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips v. AWH Corp.*, 415 F.3d at 1314-15.

G. "[W]herein the ballast portion spans a distance along the vertical meridian of at least 50% of the respective dimensions of the superior, intermediate, and inferior portions as measured along the vertical meridian." ('746 patent, claim 8).

The parties disagree on what it means to have a ballast portion that "spans a distance . . . of at least 50% of the respective dimensions of the superior, intermediate, and inferior portions." The best way to understand the dispute is through an example. Exhibit F, at 1, shows a superior, intermediate, and inferior portion of an inner zone. Each zone is 4mm in its vertical dimension. CIBA maintains that the ballast portion must be present in at least 2mm (i.e., at least 50%) of each of the three portions. Ex. F at 3. CooperVision maintains that as long as the ballast portion

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is present in at least 6mm of the vertical dimension of the inner zone, and thus 50% of the respective vertical dimensions of the superior, intermediate, and inferior zones, the limitation is satisfied. Ex. F at 2. This encompasses a number of different embodiments, some examples of which are attached as Ex. F, at 4-6.

CIBA's proposed definition of claim 8 creates an unprincipled limitation. Claim 8 of the '746 patent depends from claim 1. Claim 1 recites that ballast portion has "a series of consecutive horizontal cross-sections" that have "substantially uniform thickness." Therefore, to satisfy claim 1 the ballast portion must be continuous. According to CIBA, to satisfy claim 8, the ballast portion must be in 50% of all three zones. If CIBA's construction is correct, the ballast portion must always span a 100% of the vertical distance of the intermediate zone and then at least some vertical distance in both the inferior and superior portions. It is only in this situation that the ballast portion can be continuous. *See* Ex. F at 6. There is nothing in the specification that suggests claim 8 should be limited to this single design.

Moreover, Claim 7 of the '746 patent, which also depends from claim 1, requires that the ballast portion be present in all three portions – superior, intermediate, and inferior. CIBA's construction of claim 8 requires this as well. If CIBA's construction were correct, claim 8 should depend from claim 7 (which it does not).

H. "Ballast Portion" ('740 patent, claim 1; '746 patent, claims 1, 4, 7, and 8) and "Prism Ballast Portion" ('903 patent, claims 29, 34, 38)

<u>CooperVision Proposed Construction</u>: "A portion of a ballast. A ballast being a surface contour of the lens that has a varying thickness to re-orient the lens."

<u>CIBA Proposed Construction</u>: "A surface contour of the lens that has a varying thickness to re-orient the lens and that has consecutive horizontal cross sections throughout the entire structure each of which has substantially uniform thickness not varying by more than approximately 30 μm or 20% of the minimum thickness in the cross section."

The parties have agreed that once the dispute regarding the definition of ballast portion is resolved, the definition of prism ballast portion will be undisputed: A prism ballast portion is "a ballast portion that includes the optic zone."

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The central difference between the proposed constructions is CIBA's desire to import a limitation that the entire ballast has "isothickness." 6:55-61 ("The term isothickness means that each of the consecutive horizontal cross sections has a substantially uniform thickness not varying by more than about 30µm or 20% "). CIBA proposed definition is inconsistent with the express teaching of the specification.

1. The Toric Patents Claim Inventions Other Than Isothickness

The Toric Patents provide a suite of techniques useful for creating high performing lenses that contain rotational stabilization structures. For example, the specification teaches that at certain meridians on the lens the width of the peripheral zone should be in a certain critical range ("Meridian Width"). 3:61-4:24. The specification also teaches designers the optimum ratio for the width of the inner zone in the superior and inferior regions of the lens ("A to B Ratio"). 4:25-34. Although the Meridian Width and A to B Ratio inventions are applicable to lenses that include isothickness, there is nothing in the specification that limits these inventions to lenses with isothickness.

Asserted claims 29, 34, and 38 of the '903 patent relate to the Edge Width and A to B Ratio inventions. Because these claims use the phrase prism ballast portion, CIBA's proposed construction improperly imports the requirement that the lenses covered by these claims exhibit isothickness, even though the claims never discuss the concept and relate to different inventions.

Moreover, Claim 31 (which depends from claim 29) and claim 36 (which depends from claim 34) adds the limitation of a ballast portion in which "each horizontal cross-section has a substantially uniform thickness not varying by more than about 30 µm or 20% " It is improper to import into an independent claim a limitation in a dependent claim. *See*, *e.g.*, *Phillips*, 415 F.3d at 1314-15; *SunRace Roots*, 336 F.3d at 1303.

CIBA may argue that there are other limitations in claims 31 and 36 beyond the concept of isothickness. Even if this were the case, however, the detailed description of isothickness in these dependent claims make clear that when the Toric Patents seek to claim isothickness, they

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do so by placing in the claim explicit language requiring isothickness. It is not appropriate to shoe horn into distinct inventions disclosed in the specification the concept of isothickness.

The term ballast portion appears throughout the claims in the '903, '740 and '746 patents. CIBA appears to accept that it should be interpreted consistently across all these claims. Only CooperVision's interpretation both remains consistent with the specification, and at the same time does create an absurdity in which claims that have nothing to do with isothickness require isothickness. 6:64-73 ("A ballasted lens provides some raised surface contour over which the eyelid wipes to reorient the lens")

2. The Specification Teaches That the Entire Ballast Need Not Have Isothickness

CIBA's definition of ballast portion requires that the entire ballast structure on the lens, as opposed to a portion of it, has isothickness. CIBA's definition is inconsistent with the description of the preferred embodiments of the isothickness invention in the specification, which only require that a specific portion of the ballast (i.e., the "ballast portion") has isothickness.

The specification teaches that the greater the isothickness in a ballast on the lens, the greater stability and comfort of the lens. However, when discussing the "preferred embodiments" of the invention, the specification recognizes that it may not be possible to design a lens in which the entire ballast has isothickness. For example, the specification notes that "the present invention provides that consecutive horizontal cross-sections . . . that possess ballast each has a substantially uniform or isothickness. . . . " 7:13-17. But it goes on to acknowledge that the invention encompasses a situation in which "one of the cross-sections . . . having ballast . . . has a substantially uniform thickness." 7:17-22. And then contrasts this with an embodiment in which "all of the cross sections . . . that possess ballast may have a uniform thickness " *Id*.

For example, Figures 5a-5d show "varying regions of substantially uniform horizontal thickness" in different portions of the inner zone of a lens. 4:60-64. According to the specification, "Figures 5a-5d illustrate several variations of the contact lens of the present invention having different ballast portions defined within the ballast zone." 10:23-25.

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Therefore, within the "ballast zone" on these lenses (*i.e.*, the portion of the lens that contains the complete ballast structure), there is an isothickness "ballast portion."

The specification provides proposed ranges of isothickness. It states that "[d]esirably, isothickness ballast surfaces are formed in at least 20% (measured as a percent of the vertical dimension), preferably at least 50%, and more preferably at least 100% of at least one" of the superior, intermediate, or inferior portions of the inner zone. 6:44-47. But it also notes that in "another embodiment, the [isothickness] ballast portion is defined within all three of the superior, intermediate, and inferior portions, or comprises the entire inner zone." 3:54-57.

As discussed in the preceding section on the peripheral zone, the dividing line between the inner zone and the peripheral zone is defined by the "ballast periphery." *See*, *e.g.*, 6:4-13; 6:21-32; Fig. 1. Indeed, it is for this reason that the specification also refers to the end of inner zone as the "end of the ballast zone." 9:29-38. Within the inner or ballast zone, the patent teaches that at least certain minimum portions of the ballast have isothickness. CIBA's definition, which requires that the entire ballast structure on the lens (and thus the entire inner zone) has isothickness, therefore excludes preferred embodiments of the patent. The Federal Circuit teaches that a definition that excludes a preferred embodiment is not appropriate. *See Primos*, 451 F.3d at 848.

I. Distance Measurement

Two limitations in the asserted claims require the measurement of the width of certain areas of the lens:

"[W]herein, along a 225° meridian, the distance between the inner zone and the peripheral edge is less than about 1.8 mm." ('903 patent, claim 29; see also claim 34)

"[W]herein a band circumscribed by the peripheral zone and around the optic zone is substantially annular, with a superior distance A being defined along the vertical meridian and within the inner zone from the optic zone to the peripheral zone, and an inferior distance B being defined along the vertical meridian and

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within the inner zone from the optic zone to the peripheral zone, and wherein $0.33A \le B \le A$." ('903 patent, claim 38)

These limitations are part of claims that relate to what the brief earlier referred to as the Meridian Width and A to B Ratio inventions. The Meridian Width claims require that the width of the peripheral zone measured at certain locations be less than certain critical values. The A to B Ratio claim requires that the width of the inner zone in the inferior portion of the lens (distance B) be not less than 33% the width of the inner zone in the superior portion of the lens (distance A), and that distance A is greater than distance B.

CooperVision and CIBA disagree about how to measure the distances described in the two limitations. CooperVision believes that the distance between two points on a contact lens should be measure by the straight line distance between these two points ("straight line"). CIBA believes that the distance should be measured over the curve between the two points (the "arc length").

For a lens designer of ordinary skill in the art as of the priority date of these claims (March 2001), the standard method of measuring length on a contact lens was the straight line distance. This stems from the fact that arc length measurements normally involved extrapolating data about the radius and curve of the arc of the interest. Given the number of measurements necessary to design a lens, the complexity of an arc length measurement made it impractical for an ordinary lens designer. Seger Decl., ¶¶13-14.

J. Molded prism ballast portion ('903 patent, claim 38)

<u>CooperVision Proposed Construction</u>: "A prism ballast portion made with front surface and back surface molds without subsequent machining or polishing."

<u>CIBA Proposed Construction</u>: "A prism ballast portion that is manufactured primarily in a mold."

The specification describes two alternative methods of placing rotational orientation structures, for example a ballast, on a lens: "the various structures are then <u>either</u> molded <u>or</u> machined from the base sphere." 5:28-30 (emphasis added). The specification draws a

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distinction between molded structures and machined structures. CIBA's proposed construction, through use of the word "primarily," allows for a molded prism ballast portion to be subsequently machined. This is inconsistent with the distinction made in the specification.

V. Conclusion

"The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Phillips*, 415 F.3d at 1316. CooperVision respectfully submits that its proposed claim constructions best vindicate the Federal Circuit's teaching.

Dated: May 15, 2007 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 15, 2007, the foregoing was served using the Court's ECF system on all counsel consenting to such service.

By: /s/ Jason G. Sheasby
Jason G. Sheasby